REMARKS

Claims 1-16 are pending in the application, as amended. Claim 1 has been amended to specifically point out that the low-profile inserter includes a release lever pivotally mounted to a retainer that is pivotable between a retaining position and a release position. Support for this amendment can be found in the paragraph numbered [0030], on page 5 of the application and in Fig. 5. Claims 2, 3, 5 and 8 have been amended such that they are consistent with amended claim 1. Claims 1, 8, 11, 14 and 16 have been amended to cancel the word, "whereby" and replace the word whereby with the word, "wherein", as was requested by the Examiner. Accordingly, new matter has been added.

Claim Rejection - 35 U.S.C. § 112

The Examiner rejected claims 1, 8, 11, 14 and 16 as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicant regards as the invention. Specifically, the Examiner argues that the word, "whereby" in these claims is not given any patentable weight and should be replaced by the word, "wherein." Applicant amended claims 1, 8, 11, 14 and 16 to cancel the word, "whereby" and has replaced the word whereby with the word, "wherein." Accordingly, applicant respectfully submits that amended claims 1, 8, 11, 14 and 16 are in full compliance with 35 U.S.C. § 112 and respectfully requests that the Examiner reconsider the above rejection of these claims.

Claim Rejections - 35 U.S.C. § 102

The Examiner rejected claims 1, 12 and 13 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,980,506 (Mathiasen). Applicant respectfully traverses this rejection.

Mathiasen discloses a subcutaneous infusion device with a housing 1 that is pivotable relative to a base 8 to facilitate mounting a connector 3 to the housing 1. Referring to Figs. 1-4, a soft cannula 2 is secured to and extends from the housing 1 into a patient's body. The connector 3 is removable from the housing 1 by actuating a locking arm 5 to disengage a bridge element 17 of the housing 1 from a barb 16 of the connector 3. The connector 3 includes a needle 14 protruding from a front face and a bore 15 that is connected to a hose 4. The hose 4

is in fluid communication with the cannula 2 which extends from a front of the housing 1 when the needle 14 is disposed through a self-sealing septum 12 within the housing 1. The housing 1 and connector 3 may be pivoted about a pivot axis relative to the base element 8.

The present invention is directed to a low-profile inserter assembly 10 for an angled infusion set having a cannula assembly including a cannula housing 28 and a cannula 26 extending from the housing 28. Referring to Figs. 1, 2, 5 and 12, the cannula 26 may be inserted subcutaneously into a patient at an angle θ. The inserter assembly 10 includes an inserter housing 12 with a bottom wall 25. A retainer 30 is slideably connected to the inserter housing 12 and moves between retracted and extended positions in a direction that is substantially parallel to the bottom wall 25. The retainer 30 is adapted to releaseably receive the cannula assembly. A release lever 60 is pivotally mounted to the retainer 30 and is pivotable between a retaining position and a release position. A base member 18 is connected to the inserter housing 12 and has a lower surface 20 that is adapted to contact an outer skin surface 22 of the patient. The lower surface 20 and bottom wall 25 form an acute angle θ that permits the subcutaneous insertion of the cannula 26 into the patient's skin 22 at the acute angle θ.

Claim 1 recites, *inter alia*, a low-profile inserter for an angled infusion set having an cannula assembly including a cannula housing and a cannula extending from the housing ... comprising: an inserter housing having a bottom wall; a retainer slideably connected to the inserter housing for movement between retracted and extended positions in a direction substantially parallel with the bottom wall ... the retainer being adapted to releaseably receive the cannula assembly; a release lever pivotally mounted to the inserter housing, the release lever being pivotable between a retaining position and a release position.

There is no teaching, suggestion or disclosure in Mathiasen of a retainer that is slideably connected to an inserter housing for movement between a retracted and extended position in a direction substantially parallel with the bottom wall of the inserter housing, a cannula assembly that is releasably received by the retainer or a release lever pivotally mounted to the retainer that is pivotable between a retaining position and a release position. Specifically, Mathiasen discloses a connector 3 that is insertable into a groove in a housing 1 between a first wall adjacent a self-sealing septum 12 (Fig. 4) and a lip at a rear of the housing 1 (Fig. 3). The

connector 3 is held relative to the housing when the locking arm 5 is engaged with the bridge element 17. To release the connector 3 from the housing 1 the locking arm 5 is depressed and the connector 3 is pivoted upwardly at its rear until a rear edge of the connector clears the rear edge of the housing 1. The connector 3 is then pulled away from the housing at an angle to a lower surface of the housing. In addition, there is no structure in Mathiasen directed to a release lever pivotally mounted to a retainer, which is pivotable between a retaining position and a release position. Further, there is no teaching suggestion or disclosure in Mathiasen of a cannula assembly that is releasably received by a retainer. The connector 3 of Mathiasen is removable from the housing 1 but the cannula 2 of Mathiasen is permanently secured to the housing 1 and not releasably received by the retainer. Based upon the above-listed arguments, Applicant respectfully requests that the Examiner reconsider and withdraw any rejection of amended claim 1, based upon anticipation by Mathiasen because Mathiasen does not teach, suggest or disclose each and every element of amended claim 1.

Claims 12 and 13 are dependent upon claim 1. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw any rejection of claims 12 and 13 based upon anticipation by Mathiasen, for the same reasons discussed above for amended claim 1.

The Examiner also rejected claims 1, 12 and 13 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,966,589 (Kaufman). The Examiner argues that Kaufman discloses each and every element of claims 1, 12 and 13. Applicant respectfully traverses this rejection.

Kaufman is directed to an intravenous catheter placement device that includes a hollow barrel member 14, an attachment plate 11 that is pivotally attached to the barrel member 14 and an elongated carrier 26 that is slideable within the barrel member 14 and carries a needle 34. Referring to Figs. 1-6, the carrier 26 and needle 34 are biased to a retracted position by a spring member 28. In use, the attachment plate 11 is positioned on a patient's skin and the barrel member 14 is pivoted to a predetermined angle such that the needle 34 may be urged into a patient's body at the predetermined angle. The carrier 26 is then urged by manual force toward an extended position such that the needle 34 passes through an opening 20b in the barrel member

14, a second opening 12 in the attachment plate 11 and into a fluid-carrying conduit of a patient's body.

Applicant respectfully submits that Kaufman does not anticipate amended claim 1. Amended claim 1, recites, *inter alia*, a low-profile inserter for an angled infusion set having an cannula assembly including a cannula housing and a cannula extending from the housing... an inserter housing... a retainer slideably connected to the inserter housing... the retainer being adapted to releaseably receive the cannula assembly; a release lever pivotally mounted to the inserter housing, the release lever being pivotable between a retaining position and a release position. Specifically Kaufman does not teach, suggest or disclose a cannula assembly that is releasable from a retainer or a release lever that is pivotally mounted to the retainer. Kaufman discloses a carrier that is secured to a needle and slideable within a barrel member for insertion into a patient's skin. The device of Kaufman does not include a cannula assembly that is releasable from the barrel housing. In addition, Kaufman does not disclose any component similar to a release lever that is pivotally mounted to a retainer that is pivotable between release and retaining positions. Based upon the above-listed arguments, Applicant respectfully requests that the Examiner reconsider and withdraw any rejection of amended claim 1, based upon anticipation by Kaufman, because Kaufman does not teach, suggest or disclose each and every element of amended claim 1.

Claims 12 and 13 are dependent upon amended claim 1. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw any rejection of claims 12 and 13 based upon anticipation by Kaufman, for the same reasons discussed above for amended claim 1.

Further, the Examiner rejected claims 14 and 15 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,368,045 (Clement). The Examiner argues that Clement discloses each and every element of claims 14 and 15. Applicant respectfully traverses this rejection.

Clement discloses a biopsy needle instrument including a housing 8 with a stylet 18 and a cannula 20 slideably received therein. Referring to Figs. 1 and 2, the housing 8 includes a forward cavity 9 within which the cannula 20 is slideably received and a rear cavity

11 within which the stylet 18 is received. The stylet 18 is mounted on a stylet retaining collar 36 that is biased by a spring 44 toward an extended position and the cannula 20 is mounted on a cannula retaining collar 38 that is biased toward an extended position by a spring 40. The stylet retaining collar 36 may be secured in a retracted position by a rearward rocker arm 48 secured to the housing 8 and the cannula retaining collar 38 may be secured in a retracted position by a forward rocker arm 46 that is also secured to the housing 8. The rearward rocker arm 48 is secured to a firing button 22, which is exposed from the housing 8. A selector switch 24 is also exposed from the housing 8 and is integral with a forward restraining projection 32 that operates with the forward rocker arm 46 and a rearward restraining projection 34 that operates with the rearward rocker arm 48.

Referring to Figs. 2-3d, in operation, the cannula retaining collar 38, stylet retaining collar 36, forward rocker arm 46, and rearward rocker arm 48 are initially positioned as is shown in Fig. 3a. The selector switch 24 may be moved in a forward direction to release engagement with the forward and rearward rocker arms 46, 48. The firing button 22 is then actuated to release the stylet retaining collar 36 and the spring 44 urges the stylet retaining collar 36 and stylet 18 toward a front of the housing 8. In the extended position, the stylet retaining collar 38 contacts the forward rocker arm 46 and causes it to rotate and release the cannula retaining collar 38. The cannula retaining collar 38 and cannula 20 are then urged toward a forward portion of the housing 8 by the spring 40. In this position, the stylet 18 and cannula are disposed in the body of a patient.

Amended claim 14 recites, *inter alia*, an inserter for an infusion set having a cannula assembly including a cannula housing and a cannula extending from the housing... an inserter housing; a retainer slideably connected to the inserter housing for movement between retracted and extended positions, the retainer being adapted to releasably receive the cannula assembly.

Applicant respectfully submits that Clement does not anticipate amended claim14. There is no teaching, suggestion or disclosure in Clement of a retainer that releaseably receives a cannula assembly. The biopsy device of Clement discloses a cannula and stylet that are not releasable from a housing that they are stored within. Based upon this argument, Applicant

respectfully requests that the Examiner reconsider and withdraw any rejection of amended claim 14, based upon anticipation by Clement.

Claim 15 is dependent upon claim 14. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw any rejection of claim 15 based upon anticipation by Clement for the same reasons discussed above for claim 14.

Claim Rejections - 35 U.S.C. § 103

The Examiner rejected claims 1-3, 5-9 and 12-15 under 35 U.S.C. § 103(a) as being unpatentable over Clement in view of Mathiasen or Kaufman. The Examiner argues that Clement discloses each and every element of the above-listed claims except for a lower surface that forms an acute angle with a housing bottom wall. The Examiner further argues that it would have been obvious to one having ordinary skill in the art to modify the device of Clement to include a lower surface that creates an acute angle with a bottom wall of a housing by combining the device of Clement with the devices of Mathiasen or Kaufman. Applicant respectfully traverses this rejection.

Applicant respectfully submits that even if Clement were modified in view of Mathiasen or Kaufman the modified Clement device would not disclose each and every element of amended claims 1 and 14. Specifically, the modified Clement device would not disclose the following elements of amended claims 1 and 14:

1. a retainer adapted to releaseably receive a cannula assembly; and
2. a cannula assembly.

The Clement, Mathiasen and Kaufman devices do not teach, suggest or disclose a retainer that is adapted to releasably receive a cannula assembly or a cannula assembly, therefore, a modified device that includes elements from Clement, Mathiasen and Kaufmann could not include these claimed elements of amended claims 1 or 14.

In addition, one having ordinary skill in the art would not modify Clement in view of Mathiasen or Kaufman to include a retainer adapted to releasably receive a cannula assembly or a cannula assembly. One having ordinary skill in the art would not make such a modification because Clement is directed to a biopsy needle instrument, which would not function properly

with the above-listed structural elements of amended claims 1 and 14. Specifically, one having ordinary skill in the art would not modify Clement to include a cannula assembly that is releasable from a retainer of a low-profile inserter because the Clement biopsy instrument is designed to remove tissue samples from a patient but not to leave a cannula assembly attached to the skin of a patient. One having ordinary skill in the art would realize that the inclusion of a releasable cannula into the device of Clement would defeat the purpose of the device of Clement, which is the extraction of tissue samples using the biopsy needle and immediately removing the biopsy needle from the patient. Specifically, one having ordinary skill in the art would realize that Clement teaches a way from releasable retention of a cannula by a moving retainer. A patient having a biopsy, for example, the prostate biopsy described in column 4 of Clement would not want a cannula assembly released from the biopsy housing to remain in the prostate.

Further, one having ordinary skill in the art would not modify Clement to include a base member with a lower surface that forms an acute angle with a bottom wall of an inserter housing such that the cannula may be subcutaneously inserted into a patient at the acute angle with respect to the skin of a patient. Such an angled insertion of a biopsy needle may increase the likelihood that the needle and/or cannula miss a tumor that the biopsy instrument of Clement is attempting to sample. Clement inserts the needle and cannula at a perpendicular angle relative to a patient's skin to minimize the distance the needle and cannula travel through a patient's soft tissue and to improve accuracy of insertion into a target tumor. Missing the tumor that is to be sampled is an undesirable result as is discussed at column 7, lines 2-8 of Clement, which may be increased by traversing an extra distance through a patient's soft tissue. In addition, directing the needle and cannula at an angle necessarily involves puncturing more of a patient's soft tissue than a perpendicular insertion, which may cause additional pain and tissue damage to a patient. Therefore, applicant respectfully submits that one having ordinary skill in the art would not modify the device of Clement to include any of the above-listed and claimed elements of amended claims 1 and 14. Based upon the above-discussed arguments, Applicant respectfully requests that the Examiner reconsider and withdraw any rejection of amended claims 1 and 14 based upon unpatentability over Clement in view of Mathiasen or Kaufman.

Claims 2, 3, 5-9, 12, 13 and 15 are dependent upon one of amended claims 1 or 14. Accordingly, Applicant respectfully submits that claims 2, 3, 5-9, 12, 13 and 15 are

patentable over Clement in view of Mathiasen or Kaufman based upon the same arguments presented above for amended claims 1 and 14. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw any rejection of claims 2, 3, 5-9, 12, 13 and 15 based upon unpatentability over Clement in view of Mathiasen or Kaufman.

The Examiner also rejected claims 1-16 under 35 U.S.C. § 103(a) as being unpatentable over Clement in view of Mathiasen or Kaufman and further in view of U.S. Patent No. 5,562,631 (Bogert). The Examiner argues that Clement in view of Mathiasen or Kaufman discloses each of the elements of these claims except for a second release member and a second release lever for releasing a cannula assembly from the retainer, which the Examiner argues is disclosed by Bogert. The Examiner further argues that it would have been obvious to one having ordinary skill in the art to modify the combined device of Clement in view of Mathiasen or Kaufman with the device of Bogert to include a second release member and a second release lever that releases the cannula assembly from the retainer. Applicant respectfully traverses this rejection.

Bogert discloses a catheter arrangement with interlocking sequence guarding members for protecting the cannula.

Applicant respectfully submits that amended claims 1 and 14 are patentable over Clement in view of Mathiasen or Kaufman and further in view of Bogert. Even if a second release member and lever were added to the modified Clement device, Applicant submits that the device claimed in amended claims 1 and 14 is not obvious in view of a modified device constructed from a combination of Clement in view Mathiasen or Kaufman because the modified device would not include each of the elements of amended claims 1 and 14 and one having ordinary skill in the art would not modify Clement to include any of the above-listed elements of amended claims 1 and 14. The modified device does not include each of the elements of amended claims 1 and 14 and one having ordinary skill in the art would not make such modifications for the same reasons discussed in response to the previous rejection. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw any rejection of amended claims 1 and 14 based upon unpatentability over Clement in view of Mathiasen or Kaufman and further in view of Bogert.

Claims 2-13, 15 and 16 are dependent upon one of amended claims 1 or 14. Therefore, Applicant respectfully submits that claims 2-13, 15 and 16 are patentable over the combination of Clement in view of Mathiasen or Kaufman and further in view of Bogert for the same reasons amended claims 1 and 14 are patentable over the above combination. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw any rejection of claims 2-13, 15 and 16 based upon unpatentability over Clement in view of Mathiasen or Kaufman and further in view of Bogert.

Information Disclosure Statement

Applicant is submitting herewith an Information Disclosure Statement ("IDS"). Applicant respectfully requests that the Examiner consider each of the references of the IDS, initial each of the references on the attached Form PTO/SB/08A indicating the consideration of each of the listed references and return the form with any subsequent communication.

CONCLUSION

In view of the foregoing Amendment and remarks, Applicant respectfully submits that the present application, including claims 1-16 is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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